

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

LAUREN FLORO,)
Plaintiff,)
)
v.) DOCKET NO: 05CV10048-REK
)
)
METABOLIFE INTERNATIONAL, INC.,)
WALGREEN CO., AND WALGREEN)
EASTERN CO., INC.,)
Defendants.)

**MEMORANDUM IN SUPPORT OF OPPOSITION OF DEFENDANTS TO PLAINTIFF'S
REQUEST FOR ENTRY OF DEFAULT, AND DEFENDANTS' MOTION FOR LEAVE TO
ALLOW DEFENDANTS TO SERVE ANSWERS LATE**

NOW COME the Defendants, Metabolife International, Inc. ("Metabolife"), Walgreen Eastern Co., and Walgreen Co. (collectively, "Walgreen"), and, pursuant to Fed. R. Civ. P. 55(c) and Local Rule 7.1, hereby oppose the Plaintiffs' Request for Entry of Default and further move for leave to serve Answers to the Plaintiff's Amended Complaint late¹. As grounds therefore, the Defendants state as follows:

Factual & Procedural Background

In this action, the Plaintiff, Lauren Floro, claims that she suffered a stroke on September 23, 2001, as a result of ingesting an over the counter product, Metabolife 356. Metabolife 356 is a product that contained ephedra group alkaloids, and was sold for use without prescription by American consumers as a dietary supplement. The Plaintiff further alleges that the product was manufactured and/or distributed by the Defendant, Metabolife International, Inc., and that she

¹ The Plaintiff's attorney granted an enlargement of the Answer deadline until Wednesday, January 26, 2005. See Plaintiff's Request for Entry of Default, Para. 8. As explained below and in the accompanying affidavit, the Defendants' counsel mistakenly believed that the Plaintiff's attorney had granted an enlargement until Friday, January 28, 2005. The Defendants' counsel received a copy of the Plaintiff's Request papers on the morning of Friday, January 28, 2005, indicating that the Plaintiff had hand-delivered the Request papers the previous day.

purchased the product from a store owned or operated by one or both of the Walgreen defendants. The Plaintiff asserts that the Defendants are liable to the Plaintiff under theories of alleged negligence, breach of warranty, strict liability, and violations of M.G.L. c. 93A.

All of the Plaintiff's claims are based on the hotly contested notion and scientifically unproven assertion that the Plaintiff's stroke could have been caused by the ingestion of Metabolife 356. At the direction of the National Institutes of Health Office of Dietary Supplements, National Centers for Complementary and Alternative Medicine (NCCAM)(which is one of the institutes and centers that make up the NIH), and Agency for Healthcare Research and Quality, the Rand Corporation conducted an exhaustive meta-analysis to research questions regarding the efficacy of herbal ephedra and synthetic ephedrine for weight loss and athletic performance. The Rand study analyzed clinical trials, herbal ephedra-related adverse events reports on file with the U.S. Food and Drug Administration, published case reports, and certain reports to Metabolife International, Inc. Based upon this review, the Rand Corporation specifically concluded that it was *unable* to determine that ephedra-containing dietary supplements resulted in *any* serious adverse events in its users. The report includes the following (with our emphasis added):

The data on adverse events were drawn from clinical trials and case reports published in the literature, submitted to the FDA, and reported to Metabolife, a manufacturer of ephedra-containing supplement products. The strongest evidence for causality should come from clinical trials; however, *in most circumstances, such trials do not enroll sufficient numbers of patients to adequately assess the possibility of rare outcomes.* Such was the case with our review of ephedrine and ephedra-containing dietary supplements. Even in aggregate, the clinical trials enrolled only enough patients to detect a serious adverse event rate of at least 1.0 per 1,000. For rare outcomes, we reviewed case reports, but *a causal relationship between ephedra or ephedrine use and these events cannot be assumed or proven.*

The data we reviewed on adverse consequences came from both clinical trials and case reports submitted to the FDA. The strongest evidence of causality should come from clinical trials; however, in most circumstances, such trials do not enroll sufficient numbers of patients to adequately assess the possibility of rare outcomes. Such was the case with our review of ephedrine and ephedra-containing dietary supplements. For rare outcomes, we reviewed case reports. *However, we could not determine definite causality from case reports.*

With these considerations in mind, the evidence we identified supports the following conclusions:

- *There were no reports of serious adverse events in the controlled trials of ephedrine or ephedra, but these studies are insufficient to assess adverse events that occurred at a rate of less than 1.0 per 1000.*
- *A large number of adverse event reports regarding herbal ephedra-containing dietary supplements have been filed with FDA. The majority of FDA case reports are insufficiently documented to make an informed judgment about the relationship between the use of ephedra-containing dietary supplements and the adverse event in question.*
- *A very large number of adverse events were reported to one manufacturer of ephedra containing dietary supplements. Nearly all of the case reports were too poorly documented to permit us to make any judgments about the potential relationship between ephedra use and the event.*
- *We identified two deaths, three myocardial infarctions, nine cerebrovascular accidents, three seizures, and five psychiatric cases as sentinel events with prior ephedra consumption; and three deaths, two myocardial infarctions, two cerebrovascular accidents, one seizure, and three psychiatric cases as sentinel events with prior ephedrine consumption. Classification as a sentinel event does not imply a proven cause and effect relationship.*

Numerous federal lawsuits around the country involving allegations of harm due to the use of ephedra products have been consolidated for the pre-trial proceedings in the matter entitled, In Re: Ephedra Products Liability Litigation, Docket 04 MD 1598 in the United States District Court (S.D.N.Y.). The Defendant, Metabolife International, Inc., is a party to that MDL proceeding, due to having been named as a defendant in cases in which a plaintiff claims to have suffered personal injuries of the same or similar nature that the Plaintiff alleges in the present case, after ingesting the Metabolife 356 product. In the MDL proceeding, Metabolife has filed a motion seeking to disqualify the plaintiff's proposed expert witnesses, on Daubert grounds. Since January 10, 2005, Judge Rakoff has been presiding over numerous days of expert testimony on this very subject matter, and the Daubert hearings are scheduled to continue into February.

Procedural History

On September 16, 2004--one week before the statute of limitations expired--the Plaintiff, filed a Complaint against the Defendants, Metabolife International, Inc. and Walgreen Co., in the Middlesex (Massachusetts) Superior Court, which action the Middlesex Superior Court assigned Civil Action No. 2004-03651-B.

On the very last day (December 10, 2004) permitted under the Tracking order issued by the Middlesex Superior Court, the Plaintiff filed an Amended Complaint, adding as a party defendant, Walgreen Eastern Co., Inc. On that same date (which was five days before the ninety-day deadline under Mass. R. Civ. P. 4(j) for serving the summons and complaint on the defendants²), the Plaintiff finally served the summons and Amended Complaint on the Defendants. As a consequence, the original Answer deadline was December 30, 2004. The

² Rule 4(j) of the Mass. R. Civ. P. requires a plaintiff to effect service of process on the defendants within 90 days from the filing of the complaint.

enlargement of time requested herein would therefore essentially amount to a four-week enlargement of time of the original deadline.

On December 29, 2004, the Defendants' counsel requested, and the Plaintiff's counsel agreed, to enlarge the original December 30 deadline by two-weeks, to Friday, January 21, 2005. The Defendant subsequently removed the case to this Court pursuant to 28 U.S.C. § 1446(a). This removal did not affect the Answer deadline.

On Friday, January 21, 2005, the Defendants' counsel had two telephone conversations with the Plaintiffs' counsel. In the first, the Defendants' counsel asked for information about the product pill bottle label, because he had just that day learned from his client that this information would help determine the identity of the manufacturer of that particular lot of product, and might effect the content of the Defendants' Answers to the Amended Complaint. The Plaintiff's attorney replied, that he thought that the Plaintiff no longer had the pill bottle, but he would endeavor to find this information out. The Defendants' counsel asked, "if I get you the Answers on Monday, is that okay?" The Plaintiff's counsel immediately replied in the affirmative. Later that day, the Plaintiff's attorney called the Defendant's counsel back and informed him that, after checking, he learned that, in fact, the Plaintiff no longer had the pill bottle. The Defendants' counsel stated that he would nonetheless like more time to consult with his clients, to determine if the Defendants might be able to determine more information about the possible manufacturing history, and that he might not be able to obtain any more information about that issue by Monday, and said that he would like to look into it more "next week," to see if the final content of the Defendants' Answers should be affected. The Defendants' counsel stated in this second conversation, that, "perhaps" if he did not have any further insight into that issue by Tuesday

(i.e., January 25, 2005), he would just serve the Answers based upon the information known as of that time. The Plaintiff's counsel indicated that this was agreeable to him.

At this point (late Friday, January 21, 2005), the Defendants' counsel expected to serve the Answers at some point during the week of January 24-28. Based upon the casual and courteous nature of the prior discussions with Plaintiff's counsel, wherein the Plaintiffs' attorney had not mentioned any need to receive the Answers by a particular date, and given the fact that the end of the week (i.e., January 28, 2005) would only amount to a four-week extension of the original Answer deadline, and in light of the fact that the filing of the Answers by the end of the week (as opposed to at any point earlier in the week) would not result in any advantage to the Defendants or prejudice to the Plaintiff in this litigation, and in light of Defense counsel's fifteen years of experience (both as plaintiff counsel and defense counsel) in dealing with opposing counsel on matters of minor professional courtesies such as this, the Defendants' counsel believed that the Plaintiff's attorney had agreed to an enlargement to the end of the week, even though he hoped to have them earlier, rather than later, in the week.

On Tuesday, January 25, 2005, the Plaintiff's counsel called the Defendants' attorney and asked about the status of the Answers. The Defendants' attorney replied, that he had been snowed out of the office on Monday, due to the weekend blizzard, and therefore had not made the final determination on the Answers, and that he would serve the Answers the following day. Despite this statement, the Defendants' counsel continued to believe that the Plaintiff's attorney had agreed to an enlargement to the end of the week. The Defendants' counsel accepts the blame for the lack of clarity in the words he used in his last two discussions with the Plaintiff's counsel. The following day (Wednesday), counsel for the Defendant was out-of-the office much longer than he had originally expected, to attend a deposition in another matter. The following day

(Thursday), after attending a client meeting in another matter that lasted from 10:00 a.m. to 2:45 p.m., the Defendants' counsel got further information from one of the Defendants, which affected the responses to the Plaintiff's Amended Complaint, and he revised the draft Answers to the Amended Complaint, to be ready for filing the next day.

Upon arrival the next morning (i.e., Friday, January 28), the Defendants' counsel received a copy of the Plaintiff's Request. The Defendants' counsel immediately called the Plaintiff's counsel and expressed surprise at the Plaintiff's Request, and asked him if he would assent to the filing of the Answers that day. The Plaintiff's counsel said he would check. A few minutes later, he called back, and said that he would not assent to this. When asked, several times, what prejudice he thought the Plaintiff would suffer by the filing of the Answers two days later than he said, in his Request, he had agreed to, he did not cite any prejudice. Instead, he said that deadlines would be meaningless, and words to the effect that "rules are rules."

Argument

Rule 55(c) of the Fed. R. Civ. P. provides: "for good cause shown the court may set aside an entry of default and, if a judgment by default has been entered, may likewise set it aside in accordance with Rule 60(b)." The standard for relief under Rule 55(c) is less demanding than its Rule 60(b) counterpart. United States v. One Urban Lot Located at 1 Street A-1, 885 F.2d 994, 997 (1st Cir. 1989) (citing Coon v. Grenier, 867 F.2d 73, 76 (1st Cir. 1989) and 10 Wright & Miller, Federal Practice and Procedure § 2692 at 471-72 (1983 and 1989 Supp.).

'Good cause' is a mutable standard, varying from situation to situation. It is likewise a liberal one - but not so elastic as to be devoid of substance. It derives its shape both contextually and in comparison with the more rigorous standard applicable to attempts to vacate judgments under Fed. R. Civ. P. 60(b); the 'good cause' threshold for Rule 55(c) relief is lower, ergo more easily overcome, than that which obtains under Rule 60(b). Thus notwithstanding the deference due to this - as other discretionary decisions, a reviewing tribunal should not stay its hand if the

district court errs by reading "good cause" too grudgingly. Nor does "an abuse of discretion need [to] be glaring to justify reversal.
..."

Coon v. Grenier, 867 F.2d 73, 76 (1st Cir. 1989) (citations omitted). "The relevant factors to be considered in determining whether there is 'good cause' are whether the default was willful, whether setting aside the default will prejudice the other party and whether there is a meritorious defense." United States v. One Urban Lot Located at 1 Street A-1, 865 F.2d 427, 429 (1st Cir. 1989).

Allowing an entry of default to be set aside on a showing of reasonable justification is in keeping both with the philosophy that actions should ordinarily be resolved on their merits, and with the command of the Civil Rules themselves. See Fed. R. Civ. P. 1 (rules "shall be construed to secure the just . . . determination of every action"). These policy considerations, we suggest, are at their zenith in the Rule 55(c) milieu. Early in the case, as when a default has been entered but no judgment proven, a liberal approach is least likely to cause unfair prejudice to the nonmovant or to discommode the court's calendar. In these circumstances, a district court should resolve doubts in favor of a party seeking relief from the entry of a default.

Coon, 867 F.2d at 76 (citations omitted).

The Plaintiff's attorney acknowledges that he had granted an enlargement of time until Wednesday, January 26, 2005, for the Defendants to serve their Answers. The Plaintiff also correctly notes that the Plaintiff's attorney and the Defendants' counsel had had several discussions over the prior weeks, in which the Plaintiffs' had granted extensions of the Answer deadline. Thus, the Plaintiff's counsel obviously knew that the defendants were preparing, and intended to file, Answers in this case. Based upon the casual and courteous nature of the prior discussions with Plaintiff's counsel, wherein the Plaintiffs' attorney had not mentioned any need to receive the Answers by a particular date, and given the fact that the end of the week (i.e., January 28, 2005) would only amount to a four-week extension of the original Answer deadline,

and in light of the fact that the filing of the Answers by the end of the week (as opposed to at any point earlier in the week) would not result in any advantage to the Defendants or prejudice to the Plaintiff in this litigation, and in light of Defense counsel's fifteen years of experience (both as plaintiff counsel and defense counsel) in dealing with opposing counsel on matters of minor professional courtesies, the Defendants' counsel believed that the Plaintiff's attorney had agreed to an enlargement to the end of the week, even though he hoped to have them earlier, rather than later, in the week. The slight delay in filing was not willful; rather, it was the result of the Defendants' counsel's misunderstanding of the length of the enlargement that the Plaintiff had agreed to in the earlier discussions. The Defendants' counsel acknowledges and accepts the fact that that misunderstanding was the result of what was, in retrospect, his own poor choice of unclear words.

The Defendants' attorney did not seek any tactical or other advantage by filing the Answers today, as opposed to a few days earlier, on January 26, 2005. In fact, the Plaintiff did not (and could not seriously) think that there would be any practical advantage to the Defendants or prejudice to the Plaintiff as a result of the filing of Answers today, especially given the fact that the Plaintiff waited until the three-year statute of limitations expired (according to the allegations in her complaint), before she filed the complaint, waited until the very last day allowed by the Massachusetts Superior Court Tracking Order to amend the complaint adding a new party defendant, and waited until five days before the expiration of the required ninety-day service period to serve the Defendants in this case. Nor would today's filing affect the Court's calendar for this case.

The Defendants have meritorious defenses in this matter, given the fact that the Plaintiff has based her claims on the hotly contested and scientifically unproven assertion that the product

at issue in this case could cause the harm she alleges. This is the currently the subject of intensive testimony in the MDL proceedings related to Ephedra products.

Given the honest mistake that led to this situation, the lack of prejudice to the Plaintiff, the lack of any effect on the Court's calendar, and the fact that the Defendants have meritorious defenses, "good cause" exists under Fed R. Civ. p. 55(c) for the Court to deny the Plaintiff's Request and grant the Defendants' Motion, thereby allowing the Defendants to serve their Answers. See One Urban Lot, 865 F.2d at 429; Coon, 867 F.2d at 76. Denying the Plaintiff's Request and granting the Defendants' Motion would further be "in keeping both with the philosophy that actions should ordinarily be resolved on their merits, and with the command of the Civil Rules themselves." Coon, 867 F.2d at 76.

Conclusion

WHEREFORE, for all of the reasons set forth herein and in the accompanying memorandum and affidavit, the Defendants, Metabolife International, Inc., Walgreen Eastern Co., and Walgreen Co., respectfully request that the Court deny the Plaintiffs' Request for Entry of Default and grant the Defendants leave to serve answers to the Plaintiff's Amended Complaint late.

Respectfully Submitted,

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